IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. **PELVIC REPAIR SYSTEM** **PRODUCTS LIABILITY LITIGATION** **THIS DOCUMENT RELATES TO:** **ETHICON WAVE 4 CASES LISTED IN DEFENDANTS' EXHIBIT A**	**Master File No. 2:12-MD-0237** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' OPPOSITION IN RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

I. INTRODUCTION

Dr. Konstantin Walmsley is a board certified urologist and practicing physician in the State of New Jersey. *See* Ex. A, Walmsley CV at 1. He is experienced in the implantation of transvaginal mesh and regularly evaluates and treats stress urinary incontinence in his clinical practice. *See* Ex. B, Walmsley Baker Rpt. at 1; Ex. C, Walmsley Phillips Rpt. at 1; Ex. D, Walmsley Ward Rpt. at 1. Dr. Walmsley has clinical experience with a variety of options to treat SUI – including mid urethral slings (synthetic and non-synthetic) and autologous fascial slings. He has both reviewed medical literature and attended training provided by Ethicon on mid-urethral slings and has explanted and performed revision procedures on mid-urethral slings. *See, e.g.*, Ex. B, Walmsley Baker Rpt. at 1-2. Dr. Walmsley is published and has given numerous presentations on urologic issues, including modern treatment options for urinary incontinence. Ex. A, Walmsley CV at 3-5. Dr. Walmsley applied his clinical experience and review of the

literature to form the opinions that Defendants now seek to exclude. These opinions rest on a reliable foundation of clinical experience supported by references to medical literature.

Dr. Walmsley presents two general opinions in his case-specific reports: (1) the risks associated with the TVT device at issue were not sufficiently addressed in that device's Instructions for Use ("IFU") at the time the plaintiff was implanted; and (2) there were safer alternative procedures available to treat stress urinary incontinence in women, including the autologous fascial sling. *See* Ex. B, Walmsley Baker Rpt. at 4-6; Ex. C, Walmsley Phillips Rpt. at 5-7; Ex. D, Walmsley Ward Rpt. at 7-9.

Dr. Walmsley's General Opinion No. 1 and General Opinion No. 2 are both reliable, relevant to this litigation, and within his expertise. Therefore, both opinions should be admitted, and Defendants' motion should be denied.

II. LEGAL STANDARD

Under Federal Rule of Evidence 702, if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods," (3) that have been reliably applied "to the facts of the case." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013). A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993).

The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the

proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm–O–Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998). All *Daubert* demands is that the trial judge make a "preliminary assessment" of whether the proffered testimony is both reliable and helpful. *In re C.R. Bard, Inc.* at 601.

This Court has consistently held that an expert who is a practicing urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU. *See, e.g., Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 U.S. Dist. LEXIS 14869, at *16 (S.D. W. Va. Feb. 7, 2015) (allowing Dr. Ostergard to testify about the risks that the mesh product posed to patients, and whether the product IFU conveyed those risks). In addition, this Court has admitted Dr. Walmsley's opinions on safer alternatives to mesh as reliable and relevant in a case involving the Pinnacle device. *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 715 (S.D. W. Va. 2014).

Here too, the Court should admit Dr. Walmsley's opinions and deny Ethicon's motion.

III. ARGUMENTS AND AUTHORITIES

A. RESPONSE TO [THE ONLY] NEW WAVE 4 ARGUMENT

The only substantive addition to Ethicon's Wave 4 brief that was not already addressed in the parties Wave 3 briefing is found in a short paragraph at the end of Ethicon's memorandum. There, Ethicon asserts: "…to the extent General Opinion No. 2 asserts that the IFU needed to include a statement that safer alternative surgical procedures exists, that opinion should be excluded as *irrelevant*." Def.'s Br. at 5 (emphasis added). Ethicon does not challenge Dr. Walmsley's qualifications with regard to any such opinions, nor does it challenge their scientific reliability—it just asserts that they could not possibly be relevant to any of the plaintiffs' claims. But Ethicon cannot credibly argue relevance where it has not provided an analysis of a single

state's law—let alone the necessary analysis of all of the applicable states' laws. As this Court is well aware, the requirements with regard to "safer alternative design" evidence differs state by state. For example, in the *Mullins* case cited by Ethicon, the Court considered and applied the law of West Virginia. *Mullins v. Johnson & Johnson*, No. 2:12-cv-02952, 2017 WL 711766 (S.D.W.Va. Feb 23, 2017). But the state law of the various jurisdictions where these Wave 4 Plaintiffs reside and/or underwent their procedures is not uniform to that of West Virginia. Before it could render the "relevance" determination sought by Ethicon, the Court would need to consider the nature of the requirements—if any—imposed by the applicable state law. As such, the Court should not rule on the "relevance" of any safer alternative design opinions proffered by Dr. Walmsley on a "general" *Daubert* motion.

B. RESPONSE TO ETHICON'S [REASSERTED] WAVE 3 ARGUMENTS

As stated above, a comparison of Ethicon's Wave 3 and Wave 4 briefs reveals that the only substantive addition to Ethicon's Wave 3 arguments contained in its recent Wave 4 challenge to Dr. Walmsley's opinions is the short paragraph discussed above. As such, Plaintiffs' arguments below substantively mirror those contained in their Wave 3 briefing.

1. Dr. Walmsley's Opinions on the IFU Are Reliable, Squarely Within His Expertise, and Admissible.

Defendants raise the issue of is whether Dr. Walmsley is qualified to opine regarding "product labeling requirements or the development of warning labels." *See* Def. Mem. at 3-4. But, this is a non-issue, because Dr. Walmsley will not be asked to offer such opinions.

Ethicon cites *Wise v. CR Bard Inc.* for the sound but irrelevant holding that additional expertise – including experience with product labeling requirements – is required to testify about what should or should not be in an IFU *under law*. Yet, *Wise* further held that "an experienced urogynecologist … may testify about the risks he perceives that the [implanted mesh product]

poses to patients and then opine that the [implanted mesh product's] IFU did not convey those risks." *Wise*, 2015 U.S. Dist. LEXIS 14869, at *41-42.

Indeed, this Court has repeatedly held, as Ethicon acknowledges, that an expert urogynecologist or urologist may testify as to the perceived risks associated with a mesh device and whether the IFU at issue conveyed those risks. *See, e.g.*, *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-01378, 2015 U.S. Dist. LEXIS 14869, at *15-16 (S.D. W. Va. Feb. 7, 2015) ("Dr. Ostergard will testify about the risks he perceives that the Avaulta poses to patients, and he will opine that the Avaulta IFU did not convey these risks. A urogynecologist like Dr. Ostergard is qualified to make this comparison."); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) ("Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU."); *see also, e.g.*, *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 145522, at *36 (S.D. Ill. Dec. 16, 2011) (denying defendant's motion to exclude testimony, ruling that "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings").

Here, Dr. Walmsley is a practicing urologist who regularly treats women with stress urinary incontinence, implants mid-urethral slings, and treats women with mesh complications. *See, e.g.*, Ex. B, Walmsley Baker Rpt. at 1-2; Ex. A, Walmsley CV. As a practicing urologist who has used mesh and non-mesh slings to treat stress urinary incontinence, Dr. Walmsley is amply qualified to testify about the risks that are associated with the devices at issue, and whether the product IFUs warned about those risks during the relevant timeframe. Dr. Walmsley is not being produced to testify as to whether or not warning labels should be required, by law, to

include these risks. Ethicon's attempt to exclude Dr. Walmsley's relevant and reliable expert testimony by expanding its scope beyond its intended boundaries is misplaced. Since Dr. Walmsley does not seek to opine on what information should have been included by law in the IFU, but merely to compare the known risks of the devices and the warnings provided in their IFUs, Ethicon's motion should be denied as moot.

In short, because Dr. Walmsley is more than qualified to compare the risks of the devices and the risks that were communicated in their IFUs, and because this information is relevant and will be helpful to the jury, Dr. Walmsley's opinions in this regard are admissible, and Ethicon's motion must be denied.

2. Dr. Walmsley's Opinion on Safer Alternative Procedures Is Relevant and Admissible.

As a practicing urologist who has implanted both mesh and non-mesh slings, Dr. Walmsley is amply qualified to educate the jury on safer alternative procedures that were available to the plaintiffs, including the autologous fascial sling. *See, e.g.*, Ex. B, Walmsley Baker Rpt. at 6, General Opinion No. 2.

Indeed, Ethicon does not challenge Dr. Walmsley's qualifications to offer such an opinion or the reliability of this expert testimony, but argues that a safer alternative procedure such as the autologous fascial sling is always irrelevant to a design defect claim. *See* Def. Mem. at 4-5. Ethicon's claim that the Plaintiffs should be forbidden to discuss any safer alternative procedures to treat stress urinary incontinence in women fails to consider the various issues to which such evidence is relevant. Evidence of safer alternative procedures compared to Ethicon's TVT products bears upon: (1) the risk-benefit analysis; (2) Ethicon's reasonableness in putting these devices on the market; and (3) punitive damages. Indeed, this Court should allow evidence related to other effective, safer alternative procedures, as they are crucial to the implanting

doctors' decisions of whether to use the TVT products, since available alternative procedures affect the risk-benefit analysis. Moreover, information on whether Ethicon's mesh devices were actually an improvement over other procedures is important for the jury to determine the reasonableness of Ethicon's behavior in continuing to market the products despite known complications.

Accordingly, the Court should deny Ethicon's motion as to Dr. Walmsley's opinion on safer alternative procedures such as the autologous fascial sling. Or, at the very least, the Court should reserve ruling on this opinion as the Court has done before, in order to allow the trial court to assess the relevance of this expert testimony firsthand and in the context of the particular state's law concerning negligence and products liability. *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016) (reserving ruling until trial on the relevancy of safer alternative procedures, as the determination of relevance is "better decided on a case by case basis").

IV. CONCLUSION

Dr. Walmsley is an experienced clinician with extensive experience in treating stress urinary incontinence and mesh complications. His general opinions are reliable, relevant, and satisfy the requirements of *Daubert*. Defendants' motion to exclude Dr. Walmsley's general opinions should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 20176, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace